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*Admitted only in Maryland *Admitted only in Virginia •Practice Limited to Federal Agencies

January 13, 2005

WRITER'S DIRECT NUMBER: (202) 772-8619 INTERNET ADDRESS: SCHWARTZ@SKGF.COM

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Appl. No. 10/829,381; Filed: April 22, 2004

For: Novel Fluorogenic or Fluorescent Reporter Molecules and Their Applications for Whole-Cell Fluorescence Screening Assays for Caspases and Other Enzymes and the Use Thereof

Inventors:

Weber et al.

Our Ref:

1735.0290006/RWE/ALS

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office:

- 1. SKGF Cover Letter;
- 2. Information Disclosure Statement;
- 3. Thirty-four (34) pages of Form PTO-1449 citing one hundred sixty-two documents;
- 4. A copy of documents AN4, AS34 and AT34; and
- 5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Steme, Kessler, Goldstein & Fox PLLC.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540; www.skgf.com

Commissioner for Patents January 13, 2005 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Aaron L. Schwartz Attorney for Applicants Registration No. 48,181

ALS/law Enclosures 353810v1

Sterne, Kessler, Goldstein & Fox PLLLC.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540: www.skgf.com

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Weber et al.

Appl. No.: 10/829,381

Filed: April 22, 2004

For: Novel Fluorogenic or Fluorescent

Reporter Molecules and Their Applications for Whole-Cell Fluorescence Screening Assays for Caspases and Other Enzymes and

the Use Thereof

Confirmation No.: 7746

Art Unit: 1642

Examiner: To be assigned

Atty. Docket: 1735.0290006/RWE/ALS

Information Disclosure Statement under 37 C.F.R. § 1.97(b)

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of all documents, except documents AN4, AS34 and AT34, were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/947,387, filed September 7, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d). Copies of documents AN4, AS34 and AT34 are included.

Except as otherwise described in this pleading, where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to

the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants would like to bring to the Examiner's attention documents AT1, AR10 AS10 and AS13. Although the exact dates of these publications were not determined, the citations should not be construed as an admission that the information was actually published prior to October 10, 1996. Applicants would like to bring to the Examiner's attention document AS23. Although the exact date of this publication was not determined, the listed citation should not be construed as an admission that the information was actually published prior to October 9, 1997.

Document AO2 is in the German language with an English language abstract. The relevance of Document AO2 can be ascertained by reference to Document AS26, which is an unverified English language abstract thereof.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Aaron L. Schwartz

Attorney for Applicants
Registration No. 48,181

Date: January 13, 2005

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

308116_1.DOC

Page 1 of 34 ATTY. DOCKET NO. APPLICATION NO. 10/829,381 1735.0290006/RWE/ALS **FORM PTO-1449** FIRST NAMED INVENTOR Weber et al. RMATION DISCLOSURE STATEMENT FILING DATE **ART UNIT** April 22, 2004 1642 **U.S. PATENT DOCUMENTS EXAMINER** DOCUMENT NUMBER DATE NAME **CLASS** SUB-CLASS FILING DATE INITIAL 08/23/1977 AA1 4,044,126 Cook et al. AB1 4,336,186 06/22/1982 Gargiulo et al. 12/21/1982 Cook et al. AC₁ 4,364,923 4,414,209 11/08/1983 Cook et al. AD1 AE1 4,522,811 06/11/1985 Eppstein et al. AF1 4,557,862 12/10/1985 Mangel et al. AG1 4,640,893 02/03/1987 Mangel et al. AH1 5,208,148 05/04/1993 Haugland et al. 07/13/1993 Haugland et al. AI1 5,227,487 11/08/1994 Haugland et al. AJ1 5,362,628 AK1 5,443,986 08/22/1995 Haughland et al. **FOREIGN PATENT DOCUMENTS** EXAMINER DOCUMENT INITIAL NUMBER DATE COUNTRY **CLASS** SUB-CLASS **TRANSLATION** Yes AL1 EP 0 285 179 B1 | 10/05/1988 Europe No Yes AM1 EP 0 528 487 A2 | 02/24/1993 Europe No Yes WIPO AN1 WO 93/04192 03/04/1993 No Yes AO1 WO 93/10461 05/27/1993 **WIPO** No Yes AP1 WO 94/06906 03/31/1994 **WIPO** No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Adams, S.R., et al., "Biologically Useful Chelators That Take Up Ca²⁺ upon Illumination," J. Am. Chem. AR 1 Soc. 111:7957-7968, American Chemical Society (1989) Alder, A., et al., "Optical sensor for the determination of cations, its use, and fluorophores therefor," AS 1 Chemical Abstracts 123:114, The American Chemical Society, Abstract No. 35266b (1995) Alnemri, E.S., et al., "Human ICE/CED-3 Protease Nomenclature," Cell 87:171, Cell Press (October ΑT 1 1996) **EXAMINER** DATE CONSIDERED EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to Applicant.

		Page 2 of 34
	ATTY. DOCKET NO. 1735.0290006/RWE/ALS	APPLICATION NO. 10/829,381
FORM PTO-1449	FIRST NAMED INVENTOR Weber et al.	
INFORMATION DISCLOSURE STATEMENT	FILING DATE	ART UNIT
	April 22, 2004	1 1642

				U.S. P	ATENT DOCUMENTS			
EXAMINER INITIAL	DOCUM NUMBE			DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,556,	992	09/17/1996	Gaboury et al.			
	AB2	5,576,	424	11/19/1996	Mao et al.			
	AC2	5,587,	490	12/24/1996	Goodrich, Jr., et al.			
	AD2	5,605,	,809	02/25/1997	Komoriya et al.			<u> </u>
	AE2	5,698,	,411	12/16/1997	Lucas et al.			
	AF2	5,714,	,342	02/03/1998	Komoriya et al.			
	AG2	5,733,	,719	03/31/1998	Jaffe et al.			
	AH2	5,773,	,236	06/30/1998	Diwu et al.			
	Al2	5,776,	,720	07/07/1998	Jaffe et al.			-
	AJ2	5,834,	,216	11/10/1998	Roizman <i>et al</i> .			
	AK2	5,843,	,635	12/01/1998	Schlossman et al.			
	1	}		FOREIGN	N PATENT DOCUMENT	S		
EXAMINER INITIAL		DOCUMENT NUMBER		DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	CA 2,119,840		09/27/1994	Canada			Yes No
	AM2	WO 96/20721		07/11/1996	WIPO			Yes No
	AN2	wo	96/36729	11/21/1996	WIPO			Yes No
	AO2	wo	98/13517	04/02/1998	WIPO			Yes X No
	AP2	WO 98/55863		12/10/1998	WIPO			Yes No
			OTHER	(Including Aut	hor, Title, Date, Pertine	ent Pages, etc.)	
	AR	2	ionophore CPP32/Ya	and antigen rec	gation of CD40 rescues Rai eptor-triggered apoptosis b e of its substrate PARP," <i>Fl</i> / 1996)	y inhibiting activa	ation of the cyste	eine protease
	AS	2	Armstrong, R.C., et al., "Fas-induced Activation of the Cell Death-related Protease CPP32 Is by BcI-2 and by ICE Family Protease Inhibitors," <i>J. Biol. Chem. 271</i> :16850-16855, The Americ Society for Biochemistry and Molecular Biology, Inc. (July 1996)					
	АТ	2			"Membrane Permeable Floor L," <i>Biol. Chem. Hoppe-Se</i>			
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	ATTY. DOCKET NO. 1735.0290006/RWE/ALS	APPLICATION NO. 10/829,381
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	Weber et al.	
INFORMATION DISCLOSURE STATEMENT	FILING DATE	ART UNIT
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INITIAL	442	NUME		DATE 12/15/1998	Jaffe et al.	CLASS	SUB-CLASS	FILING DATE
	AA3	5,849	,513	12/15/1998	Jaπe et al.			
	AB3	5,871	,946	02/16/1999	Lucas et al.			
	AC3	5,897	,992	04/27/1999	Fearnhead et al.			
	AD3	5,908	,750	06/01/1999	Reed et al.			-
-	AE3	5,976	,822	11/02/1999	Landrum et al.			
	AF3	6,037	,137	03/14/2000	Komoriya et al.			
	AG3	6,048	,703	04/11/2000	Siman et al.			
	AH3	6,075	,020	06/13/2000	Cincotta et al.			
	Al3	6,077	,684	06/20/2000	Kravtsov		· · · · · · · · · · · · · · · · · · ·	
,	AJ3	6,200	,969 B1	03/13/2001	Fritz et al.			
 	AK3	6,251	,614 B1	06/26/2001	Fritz et al.			
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EXAMINER INITIAL			OUMENT MBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	wo	98/57664	12/23/1998	WIPO			Ye:
	АМЗ	WO 99/18856		04/22/1999	WIPO			Yes No
	AN3	wo	00/04914	02/03/2000	WIPO			Ye:
	AO3	wo	00/07017	02/10/2000	WIPO			Yes No
	AP3	WO 00/45165		08/03/2000	WIPO			Yes No
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	AR	3	Bonneau, I Based on S (January 1	Structure-Activity	gn of Fluorogenic Peptide S Relationship Studies," <i>Ana</i>	Substrates for Hoalyt. Biochem. 25	uman Cytomega 55:59-65, Acade	lovirus Protease mic Press
	AS	<u>3</u>		logical Basis of T	, B.A., "Chemotherapy of N herapeutics. Ninth Edition,			
	АТ	3		F.S., and Duff, Cublishers (UK) Ltd	5.W., "Interleukin 1: the first d. (1990)	t interleukin," <i>Imi</i>	munol. Today 11	1:13-20, Elsevier
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	Weber et al.	
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				00/10/2001	Zhang et ar.		<u> </u>		
	AB4	6,270,9	80 B1	08/07/2001	Fritz et al.				
	AC4	6,335,4	29 B1	01/01/2002	Cai et al.				
	AD4	6,342,6	11 B1	01/29/2002	Weber et al.				
	AE4	2002/0	076733 A1	06/20/2002	Kasibhatla et al.				
	AF4	6,462,0	41 B1	10/08/2002	Cai et al.				
	AG4	2003/0	027229 A1	02/06/2003	Kasibhatla et al.				
	AH4	2003/0	208037 A1	11/06/2003	Zhang et al.				
	Al4	6,518,0	32	02/11/2003	Fritz et al.				
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	AL4		1/79187	10/25/2001	WIPO			Yes No	
	AM4	WO 02/12545		02/14/2002	WIPO			Yes	
	AN4	wo 9	6/33209	10/24/1996	WIPO			Ye: No	
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	AP		OTHER (I	cluding Aut	hor, Title, Date, Pertine	nt Pages, etc.	<u> </u>	No	
	AR	4	Dilanni, C.L	, et al., "In Vitro J. Biol. Chem.	Activity of the Herpes Sim 268:25449-25454, The Am	plex Virus Type	1 Protease with		
	AS		Dinarello, C.A., "Interleukin-1 and Interleukin-1 Antagonism," <i>Blood 77</i> :1627-1652, W. B. Saunders Company (1991)						
	АТ				cture of the human adenov L Press Limited (April 1996		with its 11 amino	acid cofactor,"	
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	ATTY. DOCKET NO. 1735.0290006/RWE/ALS	APPLICATION NO. 10/829,381
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	AR	<u>5</u>	Diouri, M., 6 271:32511- 1996)	et al., "Cleavage 32514, The Ame	Efficiency by Adenovirus Protection Society for Biochemistry	tease Is Site-o y and Molecul	dependent," <i>J. E</i> lar Biology, Inc.	Biol. Chem. (December
	AS	<u>5</u>	Rate Assay	with a Potential	asensitive Human Immunodef for Monitoring Blood Levels o Syndrome Patients," <i>Analyt. E</i>	f Protease In	hibitors in Acqui	red
	AT	<u>5</u>			., "A Matter of Life and Cell De ement of Science (August 199		e 281:1317-1322	2, American
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	ATTY. DOCKET NO. 1735.0290006/RWE/ALS	APPLICATION NO. 10/829,381	
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	AR	<u>6</u>	Friesen, C., apoptosis in	et al., "Involven leukemia cells,	nent of the CD95 (APO-1/Fas " <i>Nature Med.2</i> :574-577, Natu) receptor/liga ure Publishing	nd system in dr Group (May 19	ug-induced 196)
	AS	<u>6</u>	Activation of	f Caspases in N	cid Triggers CD95 (APO-1/Fa euroectodermal Tumors," <i>Cal</i> earch (November 1997)	s)- and p53-ir ncer Res. 57:	ndependent Apo 1956-4964, Ame	ptosis via erican
	AT	<u>6</u>	Gamen, S. o activation in (November	a Fas-independ	cin-induced apoptosis in hum dent way," <i>FEBS Lett. 417</i> :360	0-364, Elsevie	er Science Publi	shers B.V.
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	ATTY. DOCKET NO. 1735.0290006/RWE/ALS	APPLICATION NO. 10/829,381
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	AR	7	Ganesh, S Fluorogen	S., <i>et al</i> ., "Flow ic Rhodamine	Cytometric Determination 110 Substrates," <i>Cytomet</i>	of Aminopeptidase try 20:334-340, Wiley	Activities in Viat y-Liss, Inc. (1995	ole Cells Using 5)
	AS	7	Gallop, M Peptide C	A., <i>et al</i> ., "Appl ombinatorial Lil	ications of Combinatorial praries," <i>J. Med. Chem.</i> 3	Technologies to Dru 7:1233-1251, Americ	ig Discovery. 1. can Chemical Sc	Background and ociety (1994)
	AT				ease of Herpes Simplex \ vth," <i>J. Virol.</i> 68:3702-371			
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	ATTY. DOCKET NO. 1735.0290006/RWE/ALS	APPLICATION NO. 10/829,381
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	AR	8	Organic Sy	M., <i>et al.</i> , "Applic nthesis, Library S Chemical Society	ations of Combinatorial Techno Screening Strategies, and Futu (1994)	ologies to Dr re Directions	ug Discovery. 2 s," <i>J. Med. Chen</i>	. Combinatorial n. 37:1385-1401,		
	AS	8	Synthesis,	Greene, T.W. and Wuts, P.G.M., "Protection For The Amino Group," in <i>Protective Groups in Organic Synthesis, Greene</i> , T.W. and P.G.M. Wuts, Eds., John Wiley and Sons, Inc., New York, NY, pp. 309-315 (1980)						
	AT 8 Griffith, E.C., et al., "Methionine aminopeptidase (type 2) is the common target for angiogenesis inhibitors AGM-1470 and ovalicin," Chem. Biol. 4:461-471, Current Biology Ltd. (June 1997)							ogenesis 1997)		
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	ATTY, DOCKET NO.	APPLICATION NO.	•
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	AR	<u>22</u>	Thornberry Medicine F	/, N.A., "The c Press Ltd. (Sep	aspase family of cysteine tember 1997)	proteases," <i>Br. Med.</i>	Bull. 53:478-49	00, Royal Society
	AS	22	Family and	/, N.A., <i>et al.</i> , ' d Granzyme B, Biology, Inc. (.	A Combinatorial Approacl " <i>J. Biol. Chem. 272</i> :1790 July 1997)	h Defines Specificitie 7-17911, The Americ	es of Members o can Society for	of the Caspase Biochemistry and
	AT	22	Toth, M.V.	, and Marshall otein Res. 36:	, G.R., "A simple, continuc 544-550, Munksgaard Inte	ous fluorometric assa emational Publishers	ay for HIV prote Limited (1990)	ase," Int. J.
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	AR	23	Tyagi, S.C. Virus-1 Pro	, and Carter, C tease," <i>Analyt</i> .	.A., "Continuous Assay of Biochem. 200:143-148, A	f the Hydrolytic Activ Academic Press, Inc	vity of Human In :. (1992)	nmunodeficiency
	AS	23	Villa, P., et Ltd. (Octob	<i>al.</i> , "Caspases er 1997)	and capase inhibitors," T	rends Biochem. Sci	. 22:388-393, E	sevier Science
	АТ	23	Webb, N.R. Meth. Cell I	, and Summer Molec. Biol. 2:1	s, M.D., "Expression of Pr 73-188, Saunders Scienti	roteins Using Recor ific Publications (19	nbinant Baculov 90)	riruses," <i>Tech J.</i>
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	AS	24	West, M.L in Pharma	., and Fairlie, [cological Sciel	D.P., "Targeting HIV-1 p nces 16:67-75, Elsevier	orotease: a test of d Science Ltd. (1995	rug-design method	lologies," <i>Trends</i>
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	AR	<u>25</u>	Yuan, J., ei Interleukin-	t al., "The C. eleg 1β-Converting Ei	jans Cell Death Gene <i>ced-3</i> Er nzyme," <i>Cell 75</i> :641-652, Cell l	ncodes a Pro Press (1993	tein Similar to N	/lammalian
	AS	<u>25</u>	Zhang, R., Synthetic P	et al., "Probing the Peptides," J. Virol.	ne Substrate Specificity of Hep. 71:6208-6213, American Soc	atitis C Virus iety for Micro	NS3 Serine Probiology (Augus	otease by Using t 1997)
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	AS	Dialog File 351, Accession No. 11813812, Derwent WPI English language abstract for WO 98/135						WO 98/13517
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	AR	27	Allen, R.T.	OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Allen, R.T. et al., "Mechanisms controlling cellular suicide: role of Bcl-2 and caspases," Cell. Mol. Life Sci. 54:427-445, Birkhäuser Verlag (May 1998)						
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	AT	27	Boudreau, Matrix," <i>Sci</i>	N., et al., "Suppr ence 267:891-8	ression of ICE and Apoptosis 93, American Association for	in Mammary E the Advancem	Epithelial Cells be	y Extracellular (1995)		
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	AR	<u>28</u>	Bradbury, I	D.A., <i>et al.</i> , "Meas	surement of the ADP:ATP rations, necrosis and apoptosis," Jo	o in human l	eukaemic cell lin	es can be used nods 240:79-92,
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	AR	<u>29</u>	Activity up	et al., "Rhodamir oon Apoptosis In Society (Octobe	ne 110-Linked Amino Acid iduction in Intact Cells," <i>B</i> er 1999)	ls and Peptides as iochemistry 38:139	Substrates to Me 06-13911, The A	easure Caspase American
	AS	AS Jones, J., et al., "Development and Application of a GFP-FRET Intracellular Caspase Assay for Drug Screening," J. Biomol. Screen 5:307-317, Mary Ann Liebert (October 2000)						Assay for Drug
	AT	29			ocine, a Microtubule-Bindi er Cells," <i>J. Natl. Canc. In</i>			
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	AS	30		Migita, K., et al., "FK506 Potentiates Steroid-Induced T-Cell Apoptosis," <i>Transplantation, 64</i> :1365-1369, Lipincott Williams & Wilkins (November 1997)						
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	AT	32	Blocked b	by Caspase-3/Cl	5/Fas-induced Ceramide PP32 Inhibition," <i>J. Biol.</i> lar Biology (September 2	Chem. 272:24308-24	ls with Slow Kine 4312, The Ameri	etics and Is Not ican Society for	
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	AR	<u>34</u>	Zhou, T., et al., "Bisindolylmaleimide VIII facilitates Fas-mediated apoptosis and inhibits T cell-mediated autoimmune diseases," Nat. Med. 5:42-48, Nature Publishing Co. (January 1999) Lendeckel, U, et al., "Induction of the membrane alanyl aminopeptidase gene and surface expression in human T-cells by mitogenic activation," Biochem J. 319:817-821, Biochemical Society/Portland Press LTD (November 1996)						
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